5 510(k) Summary

5.1 Submitted by:

Owner:	Medical Engineering Development Solutions, Inc. 11060 Irma Drive Northglenn, Colorado 80233
Contact Person:	Tim Coressel V.P. Engineering Office Phone: (303) 452-0484 Cell Phone: (303) 563-9263
Date of Summary Preparation:	June 12, 2013

5.2 Device Identification:

Trade Name of Device:	*sharpsCAN™*
Common Name:	Sharps Container
Classification Name:	MMK Accessory to hypodermic single lumen needles
CFR Reference:	21CFR 880.5570- Class II
Classification Panel:	General Hospital

5.3 Predicate Device Identification

Substantial equivalence is being claimed to the following legally marketed device:

Trade Name:	Demolizer #47 1 Gallon Point of Generation Sharps Container (K982781)
Common Name:	Sharps Container
Classification Name:	MMK Accessory to hypodermic single lumen needles
CFR Reference:	21CFR 880.5570- Class II
Classification Panel:	General Hospital

5.4 Description of Device

The *sharpsCAN™* is a disposable sharps container that is intended for the safe disposal of used medical sharps. This *sharpsCAN™* is marketed as one model.

- *sharpsCAN™* Model 1 pint,

The *sharpsCAN™* container is stable, closable, puncture resistant, impact resistant, and leak-proof on both the sides and bottom. The *sharpsCAN™* uses a vertical opening for the disposal of sharps and is intended to be used in an upright position during use with the required wall mount unit accessory.

Performance testing consisted of confirming the key safety and reliability aspects of the *sharpsCAN™* container. Four types of performance tests were performed:

- Puncture Resistance Testing- According to ASTM F2132-01
- Leak-Proof Testing- According to 29 CFR 1910.1030
- Toppling Resistance – According to CSA Z316.6-07
- Impact Resistance and Spillage Testing

The performance test results have proved the *sharpsCAN™* not only met but exceeded in one case performance testing according to its design specifications and is substantially equivalent to the predicate device.

5.5 Indications For Use

The *sharpsCAN™* Model 1 Pint required to be used with a wall mount unit accessory is intended for single use and for the disposal of contaminated medical sharps in health care facilities. This device is not intended for areas with unsupervised patient access.

5.6 Predicate Device

The *sharpsCAN™* containers are similar in design and intended use to the Demolizer #47 1 Gallon Point of Generation Sharps Container (K982781). Substantial equivalence to the predicate device was evaluated according to the criteria identified in the FDA guidance document "Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Sharps Containers," issued in October , 1993.

Tables 5-1 shows the device comparisons of the *sharpsCAN™* and the predicate device respectively.

	sharpsCAN™	Demolizer #47
510(k) Number	TBD	K982781
Construction	3 Piece Construction	3 Piece Construction
Material	Tin plated steel	Tin plated steel
Sharps Closure	Metal Cover	Metal Cover
Sharps Access	Vertical Inlet	Vertical Inlet
Geometry	Cylindrical	Cylindrical
Leak Proof	Yes	Yes
Puncture Resistance	Yes	Yes
Non-sterile	Yes	Yes
Single Use	Yes	Yes
Stability Testing	Yes	No
Impact & Spillage Testing	Yes	No

Aperture Dimension	2.5"	2-3/8"
Temporary/Permanent Closure	Both	Both
Mechanism to Prevent Hand/Finger Access	No	No
Mechanism to Prevent Spillage	No	No
Mechanism to Prevent Overfilling	Yes	Yes
Description of Accessories	Yes	No
Intended Use	Intended for the disposal of contaminated medical sharps in health care facilities.	Intended for clinical, non-clinical healthcare settings such as laboratories, dentists' office, doctor's office, corporate clinics and nursing homes.

Table 5-1.

5.7 Design and Materials

The design and construction of the ***sharpsCAN™*** and the predicate device are similar. They both are of a three piece constructed design using seam welded tin plated steel with a tin plated steel metal cover lid.

They both use a vertical opening for the disposal of sharps waste.

5.8 Description of Accessory

The wall mount unit is a required accessory intended to be used with the ***sharpsCAN™***. The accessory is a fixture secured to a stable vertical surface providing a restrictive aperture and a secured lockable containment for the ***sharpsCAN™*** .

The *sharpsCAN™* is required to be used with the wall mount unit accessory.

5.9 Conclusion

The *sharpsCAN™* is substantially equivalent to the predicate device based on the descriptive data, compliance with standards and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 23, 2013

Medical Engineering Development Solutions, Incorporated
Mr. Tim Coressel
Vice President Engineering
11060 Irma Drive
NORTHGLENN CO 80233

Re: K123807
Trade/Device Name: SharpsCAN™
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: MMK
Dated: June 12, 2013
Received: June 14, 2013

Dear Mr. Coressel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID

FOR

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use Statement

Indications for Use

510(k) Number: K123807

Device Name: *sharpsCAN™*

Indications for Use:

The *sharpsCAN™* Model 1 Pint required to be used with a wall mount unit accessory is intended for single use and for the disposal of contaminated medical sharps in health care facilities. This device is not intended for areas with unsupervised patient access.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __XX___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Sreekanth Gutala -S
2013.07.18 15:12:36 -04'00'

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K123807